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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,288	04/16/2004	Janusz Marcinkiewicz	JMA01	4290

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EXAMINER	
ISSAC, ROY P	
ART UNIT	**PAPER NUMBER**
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/825,288	MARCINKIEWICZ ET AL.	
	Examiner	Art Unit	
	Roy P. Issac	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the application

Acknowledgment is made of applicant's claim for foreign priority to under POLAND P - 359792 filed on 04/22/2003 and POLAND P - 367052 filed on 04/07/2004 under 35 U.S.C. 119(a)-(d).

This Office Action is in response to Applicant's amendment/ remarks/ response filed 3/27/2007 , wherein claims claims 1, 3, 5-9, 11, 14, 18 and 19 have been amended, and new claim 20 have been added. Paragraphs 17-19, 32-33, 35 and examples 1-2 of the specification were also amended. Claims 1-20 are currently pending and are examined on the merits herein.

Rejections Withdrawn

Applicants' amendment correcting the term from "cetomakrogel" to "cetomacrogol" overcomes the objection to claims 11, 14 and 18 with regard to the misspelled word.

Applicant's amendment deleting the phrase "inhibiting pathogenic bacteria and fungi growth", filed 3/27/2007 overcomes the rejection(s) of claim(s) 1-2 under section 112, first paragraph. Therefore, the rejection has been withdrawn.

Applicant's amendment deleting the phrase "inhibiting pathogenic bacteria and fungi growth", filed 3/27/2007 overcomes the rejection(s) of claim(s) 1-2 under section 103, over Nagl in view of Yazdanbaksh. Therefore, the rejection has been withdrawn.

The following is are new grounds of rejection necessitated by applicants amendments:

Specification

The amendment filed 3/27/2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The amendments broadens the original disclosure by adding the phrase "causing pathological dermal conditions, especially acne", and changing "ethyl cellulose" to "methyl cellulose" in paragraph 17 changes the scope of the specification from original filing. Paragraph 33 is also amended to change "ethyl cellulose" to "methyl-cellulose". The changes correcting the term "cetomacrogol" is not considered to introduce new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant's amendment with respect to claim 20 herein has been fully considered, but is deemed to insert new matter into the claims since the specification as originally filed does not provide support for applicants' claim for the "prevention of acne". The description as originally filed does not provide support for the sub-genus as instantly claimed. The court held that "subgenus range was not supported by generic disclosure and specific example within the subgenus range"; See e.g. *In re Lukach,* 442 F.2d 967, 169 USPQ 795 (CCPA 1971); the court also held that "a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads" (see *In re Smith*, 458 F.2d 1389,1395, 173 USPQ 679, 683 (CCPA 1972). See also MPEP 2163.

Consequently, there is nothing within the instant specification which would lead the artisan in the field to believe that Applicant was in possession of the invention as it is

now claimed. See *Vas-Cath Inc. v. Mahurkar*, 19 USPQ 2d 1111, CAFC 1991, see also *In re Winkhaus*, 188 USPQ 129, CCPA 1975.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for composition comprising taurine bromamine or the treatment of acne, does not reasonably provide enablement for a composition for the prevention of acne. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention:

The invention related to a microbicidal composition comprising taurine bromamine, cetomacrogol and preservatives.

The relative skill of those in the art:

The relative skill of those in the art is high, with a typical practitioner having obtained a PhD, M.D. or equivalent advanced degree.

The amount of direction or guidance presented and the presence or absence of working examples:

The specification does not provide any examples of the prevention of acne. Furthmore, the applicants have not provided any guidance as to how acne can be prevented in the specification. As discussed in the rejection for new matter, above, prevention of acne is not supported by the specification.

The breadth of the claims and the predictability or lack thereof in the art: The instant claimed invention is highly *unpredictable* as discussed below:

Prevention of acne is not the same as the treatment of a disease condition. In order to prevent a disease, as opposed to merely delaying or reducing its symptoms, a

treatment must either render the subject completely resistant to said disease after a single treatment or a limited number of treatments, or else, when continued indefinitely, continue to completely suppress the occurrence of said disease. In order to practice a preventative method, one of skill in the art must know the answer to several questions in addition to the effectiveness of the therapy in short-term relief of symptoms, including:

1) What is the duration of a single course of therapy? How often must the therapy be administered to completely suppress the disease?

2) Does the subject develop tolerance to the therapy over time? Does the disease eventually progress to a point where the therapy is unable to completely suppress all symptoms?

3) What are the long-term effects of the therapy? Does it cause progressive damage to the kidneys, liver, or other organs? Does the active agent accumulate in the subject's tissues? Is the minimum dose necessary to completely prevent the disease safe for long-term administration? Are there any steps that can be taken to reduce side effects?

For this reason, many of the therapies that are useful for treating a disease are not useful preventing the disease. For example, antibiotics, chemotherapeutics and antiviral drugs are not normally administered to healthy subjects in order to prevent the development of infection or cancer. Thus, it is highly unlikely that any of the occurances of ance can be prevented by the administration of the compositions of the instant application.

The quantity of experimentation necessary:

In order to determine whether the claimed method can prevent acne, one of ordinary skill in the art will need to answer the questions posed above, which will require significant intellectual and financial input, and an effort that will be collaborative in nature with clinical physicians, organic chemists and biochemists involved, resulting in enormous burden on one of skill in the art to practice the invention as claimed.

Thus, the specification fails to provide clear and convincing evidence in sufficient support of the compositions for the prevention of acne as claimed.

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the *Wands* factors as discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in ***undue experimentation*** to practice the invention commensurate in scope with the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 1 and 3 recites the broad recitation “pathological dermal conditions”, and the claim also recites “especially in treatment of acne” which is the narrower statement of the range/limitation.

The following are new or modified rejections necessitated by Applicant's amendment filed 3/27/2007, wherein the limitations in pending claims 1, 3, 5-9, 11, 14, 18 and 19 as amended now have been changed and claim 2 depend from claim 1 and

claims 4-19 depend from claim 3. The limitations in the amended claims have been changed and the breadth and scope of those claims have been changed. Therefore, rejections from the previous Office Action, mailed 9/11/2006, have been modified and are listed below.

Claim Objections

Claim 19 is objected to because of the following informalities: Claim 19 recites, "contains further a lipophyllic phase – liquid paraffin, acetyl alcohol and an (sic) hydrophyllic phase – propylene glycol". The recitation does not indicate whether the claim is open to other compounds or compositions that can be considered either hydrophilic or lipophilic. Appropriate correction is required.

Response to Arguments

Applicant's arguments filed 3/27/2007 have been fully considered but they are not persuasive. In view of applicants amendments it is still not clear whether the claim is a Markush type claim that is limited to the rectied lipophyllic phase and the recited hydrophyllic phase. The use of the dash to further limit claim might also be rejected as a broad limitation followed by a narrow limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3-6 and 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Yazdanbakhsh et. al. (PTO-892; Cited by the examiner).

Yazdanbakhsh et. al. discloses the use of taurine bromamine as an agent against the parasitic worm *Schistosomula mansoni* and *S. haematobium*. (Abstract and Page 106, Column 1, lines 1-5). Yazdanbakhsh et. al. further discloses the use of 10μM and 100μM taurine chloramines and taurine bromamine. (Page 107, Column 2, Figure 1). Yazdanbakhsh et. al discloses the use of taurine bromamine in Dulbecco's MEM buffer, a buffer in the physiological pH range.

The recitations, "for application to human skin for the treatment of pathological dermal conditions, especially in treatment of acne", "microbicidal composition", "main ingredient of soap used for disinfecting a human skin", "used as a medicine in treatment of pathological dermal conditions, especially in treatment of acne", "is used as a cosmetic in treatment of pathological dermal conditions, especially in treatment of acne" are considered recitation of intended use of taurine bromaine. Note that it is well settled that "intended use" of a composition or product, will not further limit claims drawn to a composition or product, so long as the prior art discloses the same composition comprising the same ingredients in an effective amount, as the instantly claimed. See,

e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Furthermore, a composition suitable for treatment of worm is considered suitable for treatment of skin.

Thus, claims 3-6 and 8-9 are anticipated by Yazdanbakhsh et. al.

Response to Arguments

Applicant's arguments filed 3/27/2007 have been fully considered but they are not persuasive. Applicants amend the claims to include the limitation, "suitable for application to human skin for the treatment of pathological dermal conditions, especially in treatment of acne". However, the added recitation merely recites the intended use of the composition. As discussed above intended uses of compositions does not further limit product claims. As such, the rejection under 102(b) is still deemed proper and is adhered to.

Claim Rejections - 35 USC § 103

Claims 7 and 10-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagl et. al. (Of Record) in view of Yazdanbakhsh et. al. (Of Record), further in view of Patel et. al. (Of Record).

Nagl et. al. teaches that taurine chloramine (also known as N-Chlorotaurine) has bactericidal properties. (Page 2507, Abstract). Nagl. et. al. further teaches that taurine chloramines has bactericidal property against a variety of different bacterial organisms,

in particular *staphylococcus aureus* and *staphylococcus epidermidis*. (Page 2509, Table 1). Nagl et. al. further teaches that taurine chloramine has bactericidal and fungicidal activity in concentration ranges of 0.55 to 55mM. (Page 2507, Column 1, Paragraph 4 to Column2, Paragraph 1).

Nagl et. al. does not expressly disclose the bactericidal or fungicidal activity of taurine bromamine or the use of taurine bromamine with other cosmetic agents, in particular cetomacrogol or talc or liquid paraffin or propylene glycol or cellulose or glycerol.

The disclosure of Yazdanbakhsh et. al. is discussed above.

Patel et. al. discloses the use of methyl cellulose, glycerol (Column 22, lines 15-25), talc (Column 22, lines 45-52), cetamacrogol, liquid paraffin, purified water and propylene glycol (Column 41, Composition example 4) with antimicrobial agents. Patel et. al. further discloses that the resistance to drugs by *staphylococcus aureus* and *staphylococcus epidermidis* are of grave concern. (Column 1, lines 39-45).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use taurine bromamine in combination with the commonly used pharmaceutical and cosmetic ingredients of claims 7 and 10-19 because a structurally similar compound, taurine chloramine, was found effective as an antibacterial agent and the '224 patent discloses the use of said ingredients in antibacterial compositions.

One of ordinary skill in the art would have been motivated to use taurine bromamine in combination with said ingredients because a structurally similar compound was found to be effective against *staphylococcus aureus* and

staphylococcus epidermidis bacteria and the "224 patent discloses the problems of drug resistance against said bacteria. As discussed above, it would have been obvious to a person of ordinary skill in the art to use a structurally similar compound for the same purpose.

Thus, claims 7 and 10-20 are obvious over the combined teachings of the prior art.

Response to Arguments

Applicant's arguments filed 3/27/2007 have been fully considered but they are not persuasive. Applicants argue that the applicants have discovered important differences between taurine chloramines and taurine broamaine. However, from taurine chloramine's well known effectiveness against *staphylococcus aureus* and *staphylococcus epidermidis* one of ordinary skill in the art would have expected Taurine bromamine to exhibit activity against said microbes.

In response to applicant's argument that the applicants discovered important differences between taurine broamaine and taurine chloramine, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). As such, the rejection under 103(a) is still deemed proper and is adhered to.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy P. Issac whose telephone number is 571-272-2674. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

6/24/07

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